

## REMARKS

### 1. *Status of claims*

After entry of the above amendment, claims 82-102 and 125 are pending. Claim 125 is new.

### 2. *Support for amendment*

Claim 125 casts into dependent form a step formerly recited by independent claim 82. No new matter has been added by this amendment.

### 3. *Claim rejections under 35 U.S.C. §112*

The Examiner rejected claims 82-102 under 35 U.S.C. §112, first paragraph, as allegedly containing new matter. Specifically, the Examiner alleged the term “intervertebral disc regenerating material” was not supported in the specification and represented new matter. Applicants traverse this rejection.

First, claim 82, as amended, does not recite “intervertebral disc regenerating material.” Second, though claims 101-102 and 125 recite “intervertebral disc regenerating material,” this term finds support in the specification at p. 6, lines 12-14 (“The three-dimensional fluid matrix may be used... may be used in combination with growth factors and/or living cells to facilitate regeneration of the structures of a degenerated [intervertebral] disc”) and p. 7, lines 8-9 (“living cells may be added to the three-dimensional matrix of cross-linked nucleus pulposus material to further promote [intervertebral] disc regeneration”). Both cited passages refer to a material (such as growth factors and/or living cells) which facilitates or further promotes intervertebral disc regeneration, *i.e.*, an intervertebral disc regenerating material. Though this phrase does not appear verbatim, it is well established that the subject matter of a claim need not be described

literally (MPEP 2163.02). For at least these reasons, Applicants request this rejection be withdrawn.

Second, the Examiner rejected claims 85 and 87 under 35 U.S.C. §112, second paragraph, as being indefinite for the difference between the terms “denaturation” and “degradation,” and the denaturation or degradation of a portion of a tissue without separation thereof, being unclear. Applicants traverse this rejection.

“Denaturation” is described at p. 13, lines 1-2, in the context of soluble cellular proteins and nucleic acids. In light of this passage, the skilled artisan would interpret “denaturation” as referring to the modification (*e.g.*, loss) of tertiary structure of proteins or a comparable conformational change of nucleic acids, without reference to changes in the primary structure (amino acid or nucleic acid sequence). “Degradation” is described at p. 12, lines 2-3, wherein sulfones and nucleases are stated as being exemplary reagents for degrading nucleic acids. In light of this passage, the skilled artisan would interpret “degradation” as referring to cleavage of the primary structure of a protein or nucleic acid (*e.g.*, the loss of amino acids or nucleotides). The skilled artisan would also find it apparent that a “portion” of a tissue can be denatured or degraded without separation of the portion from the remainder of the tissue, *e.g.*, proteins can be denatured without denaturation of a nucleic acid, *etc.* In summary, the skilled artisan would find “denaturation” and “degradation” to be distinct terms with clear meanings, and performing of either action on a portion of a tissue without separation thereof to be a clear and meaningful concept. Hence, Applicants request this rejection of claims 85 and 87 be withdrawn.

The Examiner also rejected claim 92 under 35 U.S.C. §112, second paragraph, as being indefinite for reciting “at least one protein” of the nucleus pulposus tissue on the ground it was unclear which protein was intended. Applicants traverse this rejection.

The skilled artisan would find the plain meaning of claim 92 to be that at least one protein present in nucleus pulposus tissue is engaged in cross-linking. No indefiniteness exists. Applicants request this rejection of claim 92 be withdrawn.

4. *Claim rejections under 35 U.S.C. §103*

The Examiner rejected claims 82-88 and 91-102 under 35 U.S.C. §103(a) as being unpatentable over Mechanic, US 5,854,397 (“Mechanic”) in view of Ferree, US 6,352,557 (“Ferree”), and claims 89-90 as being unpatentable over Mechanic in view of Ferree and Moore et al., US 6,350,732 (“Moore”). In light of the Declaration under 37 CFR 1.131 by Jeffrey W. Moehlenbruck and John P. Ranieri enclosed herewith, Ferree is not prior art against the present claims under 35 U.S.C. §102(e). Therefore, Applicants request the rejections of claims 82-88 and 91-102 and 89-90 be withdrawn.

5. *Conclusion*

Applicants submit all pending claims are in condition for allowance. The Examiner is invited to contact the undersigned attorney at (713) 934-4094 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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